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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/576,030 | 04/13/2006 | Masanori Yamaguchi | TOYA149001APC | 2081 |
| 20995 | 7590 | 12/09/2008 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | LAU, JONATHAN S | |
| 2040 MAIN STREET | | | | |
| FOURTEENTH FLOOR | | | ART UNIT | PAPER NUMBER |
| IRVINE, CA 92614 | | | 1623 | |
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| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 12/09/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/576,030 | YAMAGUCHI ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan S. Lau | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 35-37 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 35-37 and 39-43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 04 Sep 2008, in which claims 35, 36, 42 and 43 are amended to change the scope and breadth of the claim; claims 37, 40 and 41 are amended to correct minor informalities; and claims 1-34, 38 and 44-47 are canceled.

This application is the national stage entry of PCT/JP04/15174, filed 14 Oct 2004; and claims benefit of foreign priority documents JAPAN 2003-353490, filed 14 Oct 2003; JAPAN 2003-353491, filed 14 Oct 2003; JAPAN 2004-018128, filed 27 Jan 2004; and JAPAN 2004-194088, filed 30 Jun 2004; currently English language translations of said foreign priority documents are not of record.

Claims 35-37 and 39-43 are pending in the current application.

Rejections Withdrawn

Applicant's Amendment, filed 04 Sep 2008, with respect to claims 35, 36, 42, 43, 45 and 46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as amended claims 35, 36, 42 and 43 do not recite the unitless term "amount" or the phrase "times larger", and claims 45 and 46 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment and Remarks, filed 04 Sep 2008, with respect to claims 35-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006) with evidence showing inherency provided by Sigma-Aldrich (Technical Information Bulletin AL-142, Sigma-Aldrich, of record) has been fully considered and is persuasive, as claim 38 is canceled, and Applicant's remarks that the metal salts Merck discloses adding so that the conversion performed in a basic environment are drawn to the step of forming the ester (page 2, paragraph 9) and said ester is separated and purified prior to the conversion to scyllo-inositol by the addition of sodium borohydride, therefore the metal salts present in the conversion to the ester are not present at that stage of the purification (page 2, paragraph 12).

This rejection of claim 38 has been **withdrawn**.

Applicant's Amendment, filed 04 Sep 2008, with respect to claims 44-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006) and further in view of Husson et al. (Carbohydrate Research, 1998, 307, p163-165, of record) has been fully considered and is persuasive, as claims 44-46 are canceled.

This rejection has been **withdrawn**.

The following are new or modified grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 35-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weser (Structure and Bonding, vol. 2, 1967, p160-180, cited in PTO-892) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006). As DE 3405663 is published in German, a machine translation of the document is provided; all citations of Merck herein refer to the machine translation. Sigma-Aldrich (Technical Information

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Bulletin AL-142, Sigma-Aldrich, cited in PTO-892) is provided as evidence of the composition of Amberlite MB-3 resin.

Merck discloses a procedure for the production of scyllo inositol ("scyllo Inosit" from myo Inosose (page 1, paragraph 8). Merck discloses the procedure using the source of boric acid, sodium borohydride (page 2, paragraph 6). Merck discloses the procedure is known to produce borate from sodium borohydride (page 2, paragraph 12) Merck discloses acidifying the scyllo-inositol-boron complex with 2N hydrochloric acid to separate the borate (page 2, paragraph 12), treating the complex of boron and scyllo-inositol with acid. Merck discloses separating the scyllo-inositaol as crystals (page 2, paragraph 13), isolating and purifying the scyllo-inositol from the acid solution. Merck discloses filtration with a cation exchanger column (page 2, paragraph 12), or a strong acidic ion exchange resin. Merck discloses crystallization by adding methanol (page 2, paragraph 12), an aqueous organic solvent.

Merck does not expressly disclose the method of producing a purified scyllo-inositol comprising a first step of forming a scyllo-inositol/boric acid by adding boric acid and a metal salt, or the boric acid and a metal salt is added in an amount by mol two times or more than of scyllo-inositol dissolved in the liquid mixture (instant claim 35). Merck does not expressly disclose the amount of boric acid and a metal salt is added in an amount two to three times the amount by mol of the scyllo-inositol dissolved in the liquid mixture (instant claim 36). Merck does not specifically disclose adjusting the pH of the mixture to 8.0 to 11.0 (instant claim 35). Merck does not specifically disclose adjusting the pH of the mixture 9.0 to 10.0 (instant claim 37). Merck does not

specifically disclose the method wherein the mixture contains myo-inositol and scyllo-inositol and is obtained by reducing scyllo-inosose (instant claim 39). Merck does not specifically disclose the method wherein method wherein the acidic solution is contacted with a strong acidic ion exchange resin and a strong basic ion exchange resin (instant claim 40). Merck does not specifically disclose the method wherein the amount of methanol is added in a volume 0.3 to 5 times the volume of the acid solution (instant claim 42). Merck does not specifically disclose the method wherein the amount of methanol is added in a volume 0.9 to 2 times the volume of the acid solution (instant claim 43).

Weser teaches borate complexes such as scyllo-inositol/diborate are well known in the prior art (page 164, paragraph 3 and figure 7). Weser teaches formation of the boric complex depends on the apparent ionization constant of boric acid (page 165, paragraph 5). Weser teaches formation of the boric complex with a saccharide or sugar alcohol is known to be performed in KCl salt solution (page 166, table 1), implicitly disclosing the use of KCl to control the ionic strength of the solution. Weser teaches formation of the boric polyol complex for the purpose of separating a mixture of carbohydrates (page 171, paragraph 2). Weser teaches formation of the boric polyol complex in the presence of a NaCl salt solution (page 171, figure 10).

Weissbach teaches scyllitol, or scyllo-inositol, forms a diborate complex with two borate moieties (page 329, right column, figure 1). Weissbach teaches reduction of scyllo-myo-inosose with sodium borohydride generates a mixture of scyllitol and myo-inositol (page 329, right column, paragraph 2). Weissbach teaches the precipitation of

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the complex of scyllo-inositol and borate (page 329, right column, paragraph 2), the separation of the complex from the mixture. Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol (page 329, left column, paragraph 3). Weissbach teaches the acidification of the complex of scyllo-inositol and borate and the contacting of the solution with the resin Amberlite MB-3 (page 330, left column, paragraph 1), a mixture of strongly acidic and strongly basic resins as evidenced by Sigma-Aldrich (Sigma-Aldrich, page 4, section 5. Amberlite Monobed Resin).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Merck in view of Weser and in view of Weissbach. All of Merck, Weser and Weissbach are drawn to the formation of borate complexes with sugar alcohols and the separation thereof. Both the inventions of Merck and Weissbach are drawn to the production of scyllo-inositol by reduction of inosose with sodium borohydride. One of ordinary skill in the art would be motivated to combine the process disclosed by Merck with the teaching of Weser and the teaching of Weissbach because Weser teaches the formation of the boric complex depends on the apparent ionization constant of boric acid and implicitly teaches the use of a KCl salt solution to maintain the ionic strength of the solution in which the boric complex is formed, and Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol. Weissbach teaches scyllo-inositol forms a diborate complex with two borate moieties, which provides guidance to one of ordinary skill to select the amount of boric acid to use relative to the amount of scyllo-inositol present. Adjustments of pH, disclosed by Merck,

and adjustments in the amount of a recrystallization solvent are generally known to one of ordinary skill in the art, and are known to be optimized by routine experimentation, see MPEP 2144.05 II.

Response to Applicant's Remarks:

Applicant's Remarks, filed 04 Sep 2008, have been fully considered and found not to be persuasive.

Applicant remarks that Merck does not teach or suggest a liquid mixture containing scyllo-inositol and a neutral sugar other than scyllo-inositol. Merck does not explicitly teach that the scyllo-inositol separated by Merck is separated from a liquid mixture containing scyllo-inositol and a neutral sugar other than scyllo-inositol. However, Weissbach teaches it is known that reduction of scyllo-myo-inosose with sodium borohydride, a substantially identical process to the process taught by Merck, generates a mixture of scyllitol and myo-inositol, a neutral sugar other than scyllo-inositol (page 329, right column, paragraph 2). "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.", see MPEP 2144.01. Therefore, while Merck does not explicitly teach or suggest a liquid mixture containing scyllo-inositol and a neutral sugar other than scyllo-inositol, one skilled in the art would reasonably be expected to draw from the teaching of Merck that a mixture of scyllitol and myo-inositol is generated and from this mixture scyllo-inositol is separated.

Applicant remarks that Merck does not teach or suggest boric acid is added into the mixture. However, it is taught within Merck that borate, , is generated *in situ* by the reaction of sodium borohydride (page 2, paragraph 12) which is equivalent to the addition of boric acid to the basic reaction mixture taught by Merck. Weissbach teaches it is known in the prior art that reduction of scyllo-myo-inosose with sodium borohydride generates a mixture of scyllitol and myo-inositol and produces borate (page 329, right column, paragraph 2). Therefore one of skill in the art would reasonably be expected to infer that adding sodium borohydride also adds borate, or boric acid.

Applicant asserts that the instantly invention produces improved results compared to the process taught by Weissbach. Weissbach teaches a 90% yield of scyllo-inositol isolated (page 330, paragraph 1). However, no evidence comparing the instant process with the process taught by Weissbach is provided. Assertion of unexpectedly improved results in absence of evidence is not persuasive.

Applicant remarks a large amount of organic solvent is used in the method taught by Weissbach, however, no limitation regarding the percent yield of purified scyllo-inositol obtained by the process or the total amount of organic solvent used is found in the claims.

Conclusion

No claim is found to be allowable.

This Office Action details new or modified grounds of rejection not necessitated by Applicant's Amendment. Accordingly, this Office Action is made **Non-Final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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